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10/522,055	08/08/2005	Michel Luc Bouchoucha	1606.72259	3964

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EXAMINER	
CWERN, JONATHAN	
ART UNIT	PAPER NUMBER
3737	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,055	BOUCHOUCHA, MICHEL LUC	
	Examiner	Art Unit	
	Jonathan G. Cwern	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-10 and 12-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-10 and 12-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 20 is objected to because of the following informalities:

In claim 20, on line 7, the word "of" should be inserted between the phrase "each said".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-10, and 12-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term "stationary" is considered new matter. This term is not found anywhere in applicant's specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 9-10, 14, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch et al. (US 6,904,308) in view of Kimchy et al. (US 2004/0015075) and Kimchy et al. (US 2002/0099310).

Frisch et al. show a method of non-invasive exploration for assessing the digestive motility and/or transit of a human or animal subject, comprising: said subject swallowing an ingestible transmitting element which is non-digestible containing means transmitting at a given fixed frequency (source 100, column 3, line 60 through column 4 line 5); measuring, at a given time using at least three reception means (antenna elements 10a through 10z, column 3, lines 10-22) distributed around said subject's trunk (belt is worn around the body, column 3, lines 13-16); determining by triangulation (column 4, lines 35-40) the position of said element (column 4, lines 10-34); defining, according to the position of said element, a data for the assessment of the digestive motility and/or transit (sensors 110 provide the data, column 3, lines 65-67). Also, the measurements corresponding to the phase shift are stored in memory means (data storage unit 22, column 3, lines 41-42); the receiving means are placed around the abdominal belt (antenna array belt 10, column 3, lines 10-22); a series of position measurements are made which are spread over time (beacon may send out an intermittent signal or transmit at the same time as the data signal, column 3 line 67 through column 4, line 9); a non-invasive exploration system for assessing the digestive motility and/or transit of a human or animal subject, in particular for the implementation of the method according to claim 1, characterized by: on the one hand: an ingestible

transmitting element which cannot be digested by said subject containing means transmitting at a given fixed frequency (source 100, column 3, line 60 through column 4 line 5); and on the other hand: receiving means comprising at least three receivers (antenna elements 10a through 10z, column 3 lines 10-22) intended to be placed around the trunk of said subject (belt is worn around the body, column 3, lines 13-16), means for processing and analyzing the position of said element (processing unit 26, column 3, lines 50-53); means for storing in the memory the phase-shift measurements made by the receivers at a given time (data storage unit 22, column 3, lines 41-42); the receivers are distributed on a belt which is able to be fixed on the trunk of the subject (antenna array belt 10, column 3, lines 10-22); the analysis and processing means (processing unit 26, column 3, line 51) include a card comprising means for analogue-to-digital conversion of the signals picked up (this is a commonly known method for manipulating or transforming data, column 2, lines 39-50) and memory means common to the three receivers and arranged on the belt (data storage unit 22); means for connecting the memory means (data storage unit 22) to the processing and analysis means (processing unit 26) and for transferring the data relating to the phase shifts measured (Figure 2 shows clearly that the processing unit 26 is connected to the data storage unit 22).

Frisch et al. fail to show measuring the phase shift of the frequency transmitted by said transmission means relative to a reference phase, and determining by triangulation on the basis of the three phase-shift measurements the position of said element; each receiver being able to measure at a given time the phase shift of said

transmission frequency relative to a reference phase; means for processing and analyzing the three phase-shift measurements made by said receivers which are able to determine, by triangulation, the position of said element.

Kimchy et al. '075 disclose a radioactive emission detector equipped with a position tracking system. Kimchy et al. '075 teach measuring the phase shift of the frequency transmitted by said transmission means, and determining by triangulation on the basis of the three phase-shift measurements the position of said element (paragraph [0116]).

Kimchy et al. '310 disclose a gastrointestinal tract sensor. Kimchy et al. '310 teach measuring the length that the sensor has traveled through the GI tract from a reference point to a site of interest ([0035]).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have had the position location system operate with the phase shift triangulation method, as taught by Kimchy et al. '075, in the device of Frisch et al. Different position determination systems are well known in the art, and it would be obvious to substitute any position determination system to locate the device within the body, as they would provide a suitable equivalent. It would further be obvious to use a reference position to aid in tracking the position of the device of Frisch et al. as taught by Kimchy et al '310. It is a well known expedient to provide baseline measurements before the procedure is carried out. Using a reference position is a well known technique for determining the position of a remote device. In the case of monitoring an ingestible capsule, it would be obvious to use the capsule in the mouth as the reference

position, as the capsule has not yet begun moving through the digestive system. This allows for a measurement from start to finish of when an object enters the digestive system to when it exits.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch et al. (US 6,904,308) in view of Kimchy et al. (US 2004/0015075), Kimchy et al. (US 2002/0099310), and Iddan et al. (WO 00/22975).

Frisch et al. show a method of non-invasive exploration for assessing the digestive motility and/or transit of a human or animal subject, comprising: said subject swallowing an ingestible transmitting element which is non-digestible containing means transmitting at a given fixed frequency (source 100, column 3, line 60 through column 4 line 5); measuring, at a given time using at least three reception means (antenna elements 10a through 10z, column 3, lines 10-22) distributed around said subject's trunk (belt is worn around the body, column 3, lines 13-16); determining by triangulation (column 4, lines 35-40) the position of said element (column 4, lines 10-34); defining, according to the position of said element, a data for the assessment of the digestive motility and/or transit (sensors 110 provide the data, column 3, lines 65-67). Also, the measurements corresponding to the phase shift are stored in memory means (data storage unit 22, column 3, lines 41-42); the receiving means are placed around the abdominal belt (antenna array belt 10, column 3, lines 10-22); a series of position measurements are made which are spread over time (beacon may send out an intermittent signal or transmit at the same time as the data signal, column 3 line 67

through column 4, line 9); a non-invasive exploration system for assessing the digestive motility and/or transit of a human or animal subject, in particular for the implementation of the method according to claim 1, characterized by: on the one hand: an ingestible transmitting element which cannot be digested by said subject containing means transmitting at a given fixed frequency (source 100, column 3, line 60 through column 4 line 5); and on the other hand: receiving means comprising at least three receivers (antenna elements 10a through 10z, column 3 lines 10-22) intended to be placed around the trunk of said subject (belt is worn around the body, column 3, lines 13-16), means for processing and analyzing the position of said element (processing unit 26, column 3, lines 50-53); means for storing in the memory the phase-shift measurements made by the receivers at a given time (data storage unit 22, column 3, lines 41-42); the receivers are distributed on a belt which is able to be fixed on the trunk of the subject (antenna array belt 10, column 3, lines 10-22); the analysis and processing means (processing unit 26, column 3, line 51) include a card comprising means for analogue-to-digital conversion of the signals picked up (this is a commonly known method for manipulating or transforming data, column 2, lines 39-50) and memory means common to the three receivers and arranged on the belt (data storage unit 22); means for connecting the memory means (data storage unit 22) to the processing and analysis means (processing unit 26) and for transferring the data relating to the phase shifts measured (Figure 2 shows clearly that the processing unit 26 is connected to the data storage unit 22).

Frisch et al. fail to show measuring the phase shift of the frequency transmitted by said transmission means relative to a reference phase, and determining by triangulation on the basis of the three phase-shift measurements the position of said element; each receiver being able to measure at a given time the phase shift of said transmission frequency relative to a reference phase; means for processing and analyzing the three phase-shift measurements made by said receivers which are able to determine, by triangulation, the position of said element; and ingesting several transmitting elements over a period of time with each element having a characteristic frequency.

Kimchy et al. '075 disclose a radioactive emission detector equipped with a position tracking system. Kimchy et al. '075 teach measuring the phase shift of the frequency transmitted by said transmission means, and determining by triangulation on the basis of the three phase-shift measurements the position of said element (paragraph [0116]).

Kimchy et al. '310 disclose a gastrointestinal tract sensor. Kimchy et al. '310 teach measuring the length that the sensor has traveled through the GI tract from a reference point to a site of interest ([0035]).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have had the position location system operate with the phase shift triangulation method, as taught by Kimchy et al., in the device of Frisch et al. Different position determination systems are well known in the art, and it would be obvious to substitute any position determination system to locate the device within the

body, as they would provide a suitable equivalent. It would further be obvious to use a reference position to aid in tracking the position of the device of Frisch et al. as taught by Kimchy et al '310. It is a well known expedient to provide baseline measurements before the procedure is carried out. Using a reference position is a well known technique for determining the position of a remote device. In the case of monitoring an ingestible capsule, it would be obvious to use the capsule in the mouth as the reference position, as the capsule has not yet begun moving through the digestive system.

Iddan et al. disclose a method for delivering a device to a target location. Iddan et al. teach, that said subject ingests several transmitting elements over a period of time, each transmitting element having a characteristic frequency (page 5, lines 10-15); that it comprises several transmitting elements intended to be ingested by said subject over a period of time (page 5, lines 10-15).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have had several transmitting elements ingested by the subject over a period of time in the device of Frisch, as taught by Iddan, with the motivation that a doctor may want to take multiple readings of a patient's physiological characteristics over a period of time to determine the proper treatment, and so multiple passes of the capsule would be necessary.

Claims 12, 13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch et al. (US 6,904,308) in view of Kimchy et al. (US

2004/0015075) and Kimchy et al. (US 2002/0099310) as applied to claims 9, 10, and 14 above, and further in view of Refael (WO 01/50941).

Refael discloses an encapsulated medical imaging system. Refael teaches that the transmitting element comprises integrated power supply means (page 14, lines 7-9); that the transmitting element comprises induced power supply means (page 14, lines 7-9); that the belt also comprises means for the induction of the power supply of said transmitting element (the vest 21 performs the same function as the belt in Frisch, page 16, lines 11-15).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made to have utilized these different types of powering means in the system of Frisch, as taught by Refael, with the motivation that some source of power must be applied to the capsule in order for it to function, and these are well known means of powering a transmitting capsule within a patient's body.

Claims 7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch et al. (US 6,904,308) in view of Kimchy et al. (US 2004/0015075) and Kimchy et al. (US 2002/0099310) as applied to claims 1 and 9 above, and further in view of Hogrefe et al. (US 5,415,181).

Hogrefe et al. disclose a multi-channel ingestible biomedical monitoring system. Hogrefe et al. teach that the amplitude of the transmission frequency of the transmission means is modulated as a function of the amplitude of a signal picked up by a sensor (s1 and s2 in Figure 1) included in the transmitting element, said sensor being able to pick

up a signal representing a physiological characteristic (abstract); that the transmitting element comprises a sensor (s1 and s2 in Figure 1) which is able to pick up a signal representing a physiological characteristic, the amplitude of the frequency transmitted by the transmission means being able to be modulated as a function of the amplitude of the signal picked up by said sensor (abstract).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used the telemetry method taught by Hogrefe, in the device of Frisch, with the motivation that some form of transmission must take place between the capsule and the belt, and this telemetry method would provide a suitable means for transmitting a signal picked up by a sensor detecting a physiological characteristic, from within a capsule in a person's body.

Claims 8 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch et al. (US 6,904,308) in view of Kimchy et al. (US 2004/0015075) and Kimchy et al. (US 2002/0099310) as applied to claims 1 and 9 above, and further in view of Iddan et al. (WO 00/22975).

Iddan et al. disclose a method for delivering a device to a target location. Iddan et al. teach, that said subject ingests several transmitting elements over a period of time, each transmitting element having a characteristic frequency (page 5, lines 10-15); that it comprises several transmitting elements intended to be ingested by said subject over a period of time (page 5, lines 10-15).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have had several transmitting elements ingested by the subject over a period of time in the device of Frisch, as taught by Iddan, with the motivation that a doctor may want to take multiple readings of a patient's physiological characteristics over a period of time to determine the proper treatment, and so multiple passes of the capsule would be necessary.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch et al. (US 6,904,308) in view of Kimchy et al. (US 2004/0015075) and Kimchy et al. (US 2002/0099310) as applied to claim 2 above, and further in view of Iddan et al. (EP 0667115).

Iddan et al. disclose an in-vivo video camera system. Iddan et al. teach, that the power supply of the transmitting element is triggered at given times (capsule can be designed to only capture images when muscles are squeezing, saving battery power.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have designed the device of Frisch so that the transmitting element only transmits at certain times, as taught by Iddan, with the motivation that this would save battery power.

Response to Arguments

Applicant's arguments filed 12/10/09 have been fully considered but they are not persuasive.

First, it should be noted that the term “stationary” is considered new matter.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In regards to applicant’s arguments that it would not be obvious to combine the references, examiner respectfully disagrees. The references are all related to the field of ingestible capsule devices. Furthermore applicant states that Kimchy II specifically discloses measuring positions of the sensors in the GI tract and that no other locations in the body are even contemplated, however examiner respectfully disagrees. Kimchy II clearly states in paragraph [0103] that "the sensor described herein may be used to detect pathologies outside of the gastrointestinal tract".

In regards to applicant’s arguments the stationary reference position, examiner respectfully disagrees. Kimchy II can measure a reference position in the GI tract, and this would include both while the capsule is stationary or moving. For example the capsule can measure the length from an aberrant structure or growth in the GI tract. Such a growth could temporarily block the capsule rendering it stationary during reference position measurement. Furthermore, as material moves through the GI tract, it can frequently become stationary and then proceed to move again due to for example the peristaltic motion of the tract.

While the prior art of record does not specifically state that the reference position is acquired in the patient's mouth, one of ordinary skill in the art would be able to measure from any reference position depending on the desired measurement course. For example, one of ordinary skill in the art wanting to measure from the time the patient swallows the capsule (simulating eating food) to when it is passed out would start the measurement at the time of swallowing, in the mouth. Any position could be used for a reference position depending on the user's design choice or desired measurement.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/
Examiner, Art Unit 3737

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737